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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,967	08/24/2000	Wu Yang	393 A US	3909

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EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 11/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/645,967	Applicant(s) Yang et al.
	Examiner Bruck Kifle, Ph.D.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 23, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above, claim(s) *42-77* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-41* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's remarks filed 9/23/02 have been received and reviewed. Claims 1-77 are still pending in this application.

Election/Restriction

Applicant's argue that claims 45 and 77 should be grouped with claims 1-41. However, claims 45 and 77 are not of the same scope as claims 1-41. Compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept.

Claims 42-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 1-41 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Regarding the phrase "substituted or unsubstituted aliphatic or acyl moiety" in the definitions of R^{28} and R^{43} (also R^{A} and R^{B}) Applicants again point to page 30, line 34-page 35, line 13 to indicate the definitions of these terms. However, one skilled in the art cannot say which substituents are permitted and which ones are not. Applicants have stated that "the rapamycin compound has proven to be unusually sensitive to change, so that seemingly small structural

modifications often have dramatic changes in chemical properties." Therefore, Applicants need to say which substituents work because "any" group would not be expected to have the same property. Regarding "acyl", Applicants state that the radical RCO- is intended. However, there is no direction as to what the "R" group is. Applicants did not say or show how any acyl group would work. Also, it is still unclear which substituents are permitted and which ones are not as the specification recites only a few examples. The same problems are also still present in the definitions of R^A and R^B.

ii) Similarly, in the definitions of R^A and R^B, the groups heteroaliphatic, aryl and heteroaryl the claims need to state which atoms are intended and how many of each are intended. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. One cannot say which atoms are present, how many of each are intended or how many rings are present. The skilled artisan should be able to say what the metes and bounds of these groups are.

iii) Regarding the metes and bounds of the "pharmaceutically acceptable derivative", Applicants say that "any pharmaceutically acceptable salt, ester, carbamate, or salt of such ester or carbamate, of such compound, or any other adduct or derivative which, upon administration to a patient, is capable of providing (directly or indirectly) a 28-epirapalog as described herein, or a metabolite or residue thereof". Applicants further say that a pyrano would be a pharmaceutically acceptable derivative. The response does not say how one skilled in the art can tell whether a given derivative would work, or when a compound is and no longer is a pharmaceutically

acceptable derivative. Should a pyrano group be a pharmaceutically acceptable derivative, then claim 1 would be rejected as being anticipated by pyran. Also, a derivative is a product by process. Applicants have not said what the process is.

In all of the above recited problems, Applicants argue that anything is embraced while stating that rapamycin has proven to be unusually sensitive to change, so that seemingly small structural modifications often have dramatic changes in chemical properties. Given this statement, enablement of how to make and how to use the entire scope of the claims are raised.

Information Disclosure Statement

The information disclosure statement filed 5/18/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

November 25, 2002

Bruck Kifle
Primary Examiner
Art Unit 1624